

### REMARKS

Withdrawn claims 8-22 and pending claim 23 have been canceled without prejudice or disclaimer. Claims 1, 3, 7, 21 and 22 have been amended. Support for the amendments to claim 1 can be found at least at page 8 (lines 7-11 and 27-31), page 11 (lines 9-11 and Table 1), page 12 (lines 23-27), page 13 (Table 2), page 16 (lines 24-25) and page 17 (lines 9-10) of the specification as filed. Claim 3 has been amended to correct a typographical error. Support for the amendments to claim 7 can be found at least at previous claim 1. Support for the amendments to claim 21 can be found at least at page 8 (lines 7-11 and 27-31), page 11 (lines 9-11 and Table 1), page 12 (lines 23-27), page 13 (Table 2), page 16 (lines 24-25) and page 17 (lines 9-10) of the specification as filed. Claim 22 has been amended to properly depend from claim 1, and to correct a typographical error. No new matter has been added.

With entry of the amendment, claims 1-4, 6, 7, 21 and 22 will be pending.

### Rejections under 35 U.S.C. § 102

Claims 1-3 and 21-23 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,522,953 to Barby *et al.* ( Barby ) as evidenced by A. Charlesby, *Solubility and Molecular Size Distribution of Crosslinked Polystyrene* ( Charlesby ). The Examiner states that in Barby, (t)he polymer material of the invention can consist of at least 90% by weight (column 2, lines 60-63) and the polymer material can be made of lightly cross-linked polystyrene. As evidenced by Charlesby, lightly cross-linked polystyrenes have the ability to dissolve in non-aqueous media. Office Action at page 3.

Applicants respectfully disagree and traverse the rejection and submit that Barby does not anticipate the amended claims.

Claim 1, as amended, recites:

Freeze-dried, water-in-oil emulsion-templated porous bodies each comprising a three dimensional open cell lattice which is soluble in non-aqueous media, said lattice containing

(a) 10 to 95% by weight of a polymeric material which is soluble in the non-aqueous media and

(b) 5 to 90% by weight of a surfactant which is soluble in the non-aqueous media, said porous bodies having an intrusion volume as measured by mercury porosimetry of at least about 3 ml/g; and comprising two types of pores:

(1) from the sublimation of solid ice from the water phase of the emulsion, and

(2) from the sublimation of the oil phase of the emulsion,

wherein a water-soluble material is incorporated into the lattice of said porous bodies to be dispersed in the non-aqueous media when said lattice dissolves, said lattice visually fully dissolving in the non-aqueous media in less than 3 minutes when 0.1g of said porous bodies are stirred with 2ml of the non-aqueous media at 20 °C.

The claim, as amended, recites that the lattice visually fully dissolves in the non-aqueous media in less than 3 minutes when 0.1g of the porous bodies are stirred with 2 mL of the non-aqueous media at 20 °C. Applicants respectfully submit that Barby does not disclose a material that would have such dissolution properties.

Barby discloses homogeneous porous cross-linked polymer blocks that have a very low density, a high capacity of absorbing and retaining liquids and, due to their cross-linked polymeric nature, an ability to carry liquids significantly better than that of hitherto known porous thermoplastic compositions. Barby at col. 2, lines 21-37. These materials are described as having an absorbency for hydrophobic liquids defined in terms of oleic acid of at least 7 cc/g. *Id.* at lines 46-47. It is also disclosed that the materials yield an absorbent block which is especially useful for the absorption of hydrophobic materials such as oils. *Id.* at column 6, lines 38-40. The Examples of Barby illustrate that the materials absorb significant amounts of hydrophobic liquids such as oleic acid or liquid paraffin. Several examples were additionally washed with either methanol or ethanol using a Soxhlet extractor (see, e.g., Examples 5 and 29). That the materials absorb hydrophobic liquids, and/or can be washed with methanol or ethanol, suggests that they do not themselves dissolve in these non-aqueous liquids. As such, Applicants submit that the materials disclosed in Barby would not visually fully dissolve in non-aqueous media in less than 3 minutes, as required by amended claim 1. The disclosure of Barby also appears to fail to teach or suggest the use of radiation to initiate or generate the cross-linking of polymer molecules, as used in Charlesby upon which the Examiner has relied regarding the solubility of lightly cross-linked polystyrene. Barby instead discloses that the polymer may be a lightly cross-linked polystyrene containing a small proportion of divinylbenzene. Barby at column 5, lines 5-6.

Applicants disagree with the Examiner's statements regarding Charlesby. Charlesby describes a theoretical derivation relating to the sol fraction of a long chain polymer as a function of the crosslinking index ( $\gamma$ ). Further, Charlesby clearly states in the Introduction that polystyrene becomes crosslinked when subjected to high energy radiation such as is present in atomic piles. Specimens of this crosslinked material are then no longer soluble in organic compounds such as benzene or toluene, but swell to an extent depending on the amount of radiation to which they have been exposed, *i.e.*, to the degree of crosslinking. (Charlesby pg. 513, lines 1-6, internal citation omitted). It follows logically that, to the extent that any crosslinking of polystyrene has been induced (e.g., by exposure to radiation adequate to

crosslink polystyrene molecules), such crosslinked material merely swells in the presence of organic compounds, and does not dissolve.

During a polymerization process, there will typically exist both a gel fraction and a sol fraction. The gel fraction is the mass fraction of the network material (e.g. polymeric material) resulting from a network-forming polymerization or cross-linking process; the gel fraction comprises a single molecule spanning the entire volume of the material sample (see Exhibit A). The sol fraction is the mass fraction of the dissolved or dispersed material, resulting from a network-forming polymerization or cross-linking process, that is constituted of molecules of finite (statistically definable) relative molecular masses (see Exhibit B). At  $t=0$  during a polymerization process however, the sol fraction will be unity and the gel fraction zero this is known as the pre-gel state (see Exhibit C). Once polymerization has begun, the process is said to be in a pre-gel regime while it progresses towards the gel point (gelation point). The pre-gel regime is a stage of a network-forming polymerization or cross-linking process that extends up to, but not beyond, the gel point. The pre-gel regime may be expressed as the length of time or the chemical conversion required to reach the gel point from the start of a polymerization or cross-linking process (see Exhibit D). The gel point is the point of incipient network formation in a process forming a chemical or physical polymer network. In both network-forming polymerization and the cross-linking of polymer chains, the gel point is expressed as an extent of chemical reaction. Furthermore, at the gel point, a solid (network) material spanning the entire system is formed (see Exhibit E).

Charlesby states that the degree of cross-linking of polystyrene is directly proportional to the radiation dose, i.e. the extent of reaction is a function of the radiation applied. Charlesby also clearly states that [t]he degree of cross-linking produced [in the polystyrene specimens] was small, and could be considered as proportional to exposure time, i.e., radiation dose. (p.518, lines 5-7). Thus, Charlesby only teaches crosslinking of polystyrene by means of exposure to radiation, and measures the solubility of the sol fraction, as a function of the degree of cross-linking such that the relationship shown in the synopsis section was derived. In the art, a skilled person will routinely remove the sol fraction from a newly created polymer by means of washing and drying of the polymer, such that when a crosslinked polymer is referred to, it is understood that this means a washed and dried polymer that has had the sol fraction removed. This is taught in Barby which discloses that the homogeneous porous cross-linked polymeric block material provided by this invention may be washed and dried to yield an absorbent block which is especially useful for the absorption of hydrophobic materials such as oils. Barby at col. 6, lines 36-40, emphasis added. Furthermore, in Examples 1-29 the

resultant polymer is dried under a dry atmosphere at 25-30 °C, and as discussed above the samples in Examples 5 and 29 are further washed with methanol or ethanol using a Soxhlet extractor before drying again.

In summary, Applicants submit that the teachings of Charlesby refer to the solubility of the sol fraction. Barby teaches washing and drying of the cross-linked polymers formed so as to remove the sol fraction. Accordingly, the references do not teach a porous body with the dissolution properties recited in amended claim 1. Claims 2, 3, 21 and 22 depend either directly or ultimately from claim 1, and therefore are not anticipated by Barby as evidenced by Charlesby for the same and similar reasons and may be further patentable for reasons that may or may not be addressed herein.

Reconsideration and withdrawal of the rejection of claims 1-3 and 21-23 under 35 U.S.C. § 102(b) are respectfully requested.

Claims 1-3, 6, 7 and 21-23 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by International Patent Publication No. WO99/00187 (Application No. PCT/US98/12797) to Kitagawa ( Kitagawa ). The Examiner argues that Kitagawa teaches the production of porous crosslinked hydrophilic polymeric microbeads wherein at least 10% are spherical and the polymeric material is 30% by weight of the emulsion. Office Action at page 5. Furthermore, the Examiner alleges that (n)onionic surfactants may be present as a type of emulsifier in an amount of 1 to about 30 wt. percent. *Id.*

Applicants respectfully traverse the rejection and submit that Kitagawa does not anticipate the amended claims.

As discussed above, amended claim 1 recites that the lattice visually fully dissolves in the non-aqueous media in less than 3 minutes when 0.1g of the porous bodies are stirred with 2 mL of the non-aqueous media at 20 °C. Applicants respectfully submit that Kitagawa does not disclose a material that would have such dissolution properties. Kitagawa discloses a process that produces porous crosslinked hydrophilic polymeric materials. Kitagawa at page 3, lines 26-27. These materials are produced by polymerizing a hydrophilic polymer from an emulsion of an oil discontinuous phase in a monomer-containing hydrophilic continuous phase. *Id.* at page 12, lines 27-29. The hydrophilic monomer phase comprises a monomer, a crosslinker, an emulsifier, and a stabilizer. *Id.* at page 13, lines 6-8. After the production of an emulsion, polymerization is initiated to produce a hydrophilic block. *Id.* at pages 23-24. The resulting solid hydrophilic polymer is then washed to remove unpolymerized components. Preferably, hydrophilic polymers are extracted with acetone for roughly a day in a Soxhlet extractor,

followed by Soxhlet extraction with methanol for about a day. *Id.* at page 26, lines 27-30. This disclosure indicates that the polymeric materials do not dissolve in these non-aqueous solvents, nor are they soluble in the oil phase of the emulsion, as if that were the case the materials would be washed away during the washing step.

For at least these reasons, Kitagawa does not anticipate amended claim 1. Claims 2-3, 6, 7 and 21-23 depend either directly or ultimately from claim 1, and therefore are not anticipated by Kitagawa for the same and similar reasons and may be further patentable for reasons that may or may not be addressed herein.

Reconsideration and withdrawal of the rejection of claims 1-3 and 21-23 under 35 U.S.C. § 102(b) are respectfully requested.

### **Rejection under 35 U.S.C. § 103**

Claims 1-4, 6, 7 and 21-23 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent Application No. 2004/0096515 to Bausch *et al.* ( Bausch ) as evidenced by U.S. Patent No. 6,147,131 to Mork *et al.* ( Mork ). The Examiner argues that Bausch *et al.* teach porous beads that have shells formed of biocompatible spherical particles linked by van der Waals forces, that (t)he shell has a plurality of pores extending there through, thus is porous, and that (s)urfactants are used including that of Triton . Office Action at page 9. The Examiner concedes that Bausch does not teach the amount of surfactant to be added, but states that it would have been obvious to optimize the amount as evidenced by Mork. *Id.* at page 10.

Applicants respectfully traverse the rejection and submit a *prima facie* case of obviousness has not been established with respect to the amended claims.

As illustrated above, amended claim 1 recites that the porous bodies are water-in-oil emulsion-templated, and that they comprise two types of pores: (1) from the sublimation of solid ice from the water phase of the emulsion, and (2) from the sublimation of the oil phase of the emulsion . Applicants respectfully submit that Bausch does not disclose such porous bodies.

Bausch teaches methods of forming colloidosomes by providing particles formed from a biocompatible material in a first solvent and forming an emulsion by adding a first fluid to the first solvent, wherein the emulsion is defined by droplets of the first fluid surrounded by the first solvent. It is also stated that (t)he method includes coating the surface of the droplets with the particles and stabilizing the particles on the surface of the

droplets to form a stable colloidosome . Bausch at [0026]. The colloidosomes are not emulsion-templated, nor do they have the two types of pores recited in amended claim 1.

As discussed above, the Examiner has cited Mork only as disclosing that surfactants must be used in concentrations above 5% to effectively stabilize an open celled structure. Office Action at page 10. Applicants submit that this disclosure of Mork does not remedy the deficiencies of Bausch as discussed above.

Accordingly, amended claim 1 is not obvious over Bausch in view of Mork. Claims 2-4, 6, 7 and 21-23 depend either directly or ultimately from claim 1, and therefore are not obvious over Bausch in view of Mork for the same and similar reasons and may be further patentable for reasons that may or may not be addressed herein.

Reconsideration and withdrawal of the rejection of claims 1-3 and 21-23 under 35 U.S.C. § 103(a) are respectfully requested.

#### **Rejections under 35 U.S.C. § 112**

Claims 1-4, 6, 7 and 21-23 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner argues that the phrase in claim 1 stating that a water soluble material and/or a water-insoluble material, neither of which is soluble in the non-aqueous media is confusing. Without acquiescing to the rejection and solely to expedite prosecution, the claims have been amended to delete and/or a water-insoluble material . Reconsideration and withdrawal of the rejection are respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicants submit that the claims are in condition for allowance. Favorable consideration of the present application is therefore respectfully requested. If a conference call would be useful in resolving issues arising from the filing of this communication, please contact the undersigned at the below-noted number.

Respectfully submitted,

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